

EPA Reg. No. 92413-10
Vol. 1



August 18, 2016

Document Processing Desk
U.S. EPA - Office of Pesticide Programs
Room S-4900
2777 South Crystal Drive
Arlington, VA 22202

Dear Sir or Madam:

Re: Tevra Brands, LLC: TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats

Tevra intends to register a new conventional pesticide product in the U.S.A., TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats. This product is proposed for registration under PRIA Category R301: Registration of a New Conventional Pesticide Product under Category R301: New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and acute toxicity and public health pest efficacy.

I have enclosed the following items to register TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats:

- Transmittal Document;
- Application Form;
- Confidential Statement of Formulae (2);
- Formulator's Exemption;
- Certification with Respect to Citation of Data;
- Data Matrix;
- Proof of PRIA Payment;
- Proposed Label Text;



- Volume 1: Group A Product Chemistry for TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats;
- Volume 2: Enforcement Analytical Methods;
- Volume 3: Group B Product Chemistry for TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats.

I trust that this information is sufficient in order to register TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats. Please do not hesitate to contact me (ohansen@tevrabrands.com) if you have any questions.

Sincerely,

Dr. Olaf Hansen (Med Vet)
Tevra Brands, LLC

TEVRA Master Label

FRONT PANEL

Cats Spot On Imidacloprid + Pyriproxyfen

[Optional text appears in brackets/parenthesis – the final label may include some or all of the optional text on front, back or side label panels]

TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats

{Market Label-the word Cat will be at least 40-75% in height of the largest letter in the primary brand name.}

{Market Label-a large clear picture of a cat in the respective weight range will be on the front panel of the label.}

{One of the following statements will appear on appropriate weight band market label on front panel as required per Agency's pet spot-on mitigation measures:}

For use ONLY on cats [[&][and] kittens] [weighing] 2 [-][to] 5 lbs. and over 8 weeks [old][of age] {0.23 ml size package}

For use ONLY on cats [[&][and] kittens] [weighing] 2 [-][to] 5 lbs. and 8 weeks [of age] or older {0.23 ml size package}

For use ONLY on cats [[&][and] kittens] [weighing] 5 [-][to] 9 lbs. and over 8 weeks [old][of age] {0.40 ml size package}

For use ONLY on cats [[&][and] kittens] [weighing] 5 [-][to] 9 lbs. and 8 weeks [of age] or older {0.40 ml size package}

For use ONLY on cats [[&][and] kittens] [weighing] [more than][over][>] 9 lbs. and over 8 weeks [old][of age] {0.80 ml size package}

For use ONLY on cats [[&][and] kittens] [weighing] [more than][over][>] 9 lbs. and 8 weeks [of age] or older {0.80 ml size package}

ONLY for cats [[&][and] kittens] over 8 weeks [old][of age] and [weighing] 2 [-][to] 5 lbs {0.23 ml size package}.

ONLY for cats [[&][and] kittens] 8 weeks [of age] or older and [weighing] 2 [-][to] 5 lbs {0.23 ml size package}.

ONLY for cats [[&][and] kittens] over 8 weeks [old][of age] and [weighing] 5 [-][to] 9 lbs {0.40 ml size package}.

ONLY for cats [[&][and] kittens] 8 weeks [of age] or older and [weighing] 5 [-][to] 9 lbs {0.40 ml size package}.

ONLY for cats [[&][and] kittens] over 8 weeks [old][of age] and [weighing] [more than] [over][>] 9 lbs {0.80 ml size package}.

ONLY for cats [[&][and] kittens] 8 weeks [of age] or older and [weighing] [more than] [over][>] 9 lbs {0.80 ml size package}.

{following text will be in addition to the above required language}

Small Cats {only for use on label for 2-5 lbs and 8 weeks or older product}

Medium Cats {only for use on label for 5-9 lbs and 8 weeks or older product}

Large Cats {only for use on label for >9 lbs and 8 weeks or older product}

ACTIVE INGREDIENTS:

Imidacloprid.....9.10%

Pyriproxyfen.....0.46%

OTHER INGREDIENTS:.....90.44%

[TOTAL 100.00%]

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See [Back][Side][Label[s]][Panel[s]] for Additional Precautionary Statements

NET CONTENT: X fl oz [Y – X fl oz applicators]

[0.0078 fl oz (0.23 mL) [tubes][vials][applicators][pipettes]]

[0.014 fl oz (0.4 mL) [tubes][vials][applicators][pipettes]]

[0.027 fl oz (0.8 mL) [tubes][vials][applicators][pipettes]]

[ABNs]

TevraPet Activate [Topicals] for Cats

Vetality Activate Plus [Topicals] for Cats

Tevrapet Activate II [Topicals] for Cats

Tevrapet Activate III [Topicals] for Cats

Vetality Avantect Plus [Topicals] for Cats

Vetality Avantect II [Topicals] for Cats

Vetality Avantect III [Topicals] for Cats

Vetality Avantect [Topicals] for Cats

Vetality Advanced [Topicals] for Cats

Evergreen II Spot on [for Cats]

Avantect II [for Cats]

Activate Plus [for Cats]

Activate Plus [for Cats]

Truveta [for Cats]

ActiGuard [for Cats]

TevraPet Activate II [Topicals] for Cats

Vetality Activate II [Topicals] for Cats

Vetality Activate III [Topicals] for Cats

Vetality Advanced II [Topicals] for Cats

Vetality Avantect II [Topicals] for Cats

Vetality Avantect Plus for Cats

Evergreen II Topicals [for Cats]

Activate II [Topicals] [for Cats]

Activate Plus [Topicals] [for Cats]

Tevrapet Avanta II [Topicals] for Cats

Tevrapet Avenger II [Topicals] for Cats

Tevrapet Advanced II [Topicals] for Cats

Tevrapet Avante II [Topicals] for Cats

Vetality Avanta II [Topicals] for Cats

Vetality Avenger II [Topicals] for Cats

Vetality Advanced II [Topicals] for Cats

Vetality Avante II [Topicals] for Cats

Vetality Avant II [Topicals] for Cats

Vetality Aventect II [Topicals] For Cats

Vetality Advocate II [Topicals] for Cats

Avante II [Topicals] for Cats

Avanta II [Topicals] for Cats

Avenger II [Topicals] for Cats

Avant II [Topicals] for Cats

Aventect II [Topicals] for Cats

Advocate II [Topicals] for Cats

AventSpot II [Topicals] for Cats

ActiSpot II [Topicals] for Cats
Advotect II [Topicals] for Cats
VETALITY Advotect II [Topicals] for Cats
Tevrapet Advotect II [Topicals] for Cats

[Begin Optional Active Ingredient Reference Statements]

{Note to Reviewer – the following is an example statement:

Compare to Advantage® II, contains same active ingredients* (or)

Contains same active ingredients as Advantage® II* (or)

Contains imidacloprid and pyriproxyfen, the active ingredients used in Advantage® II*

*[This product is not manufactured by Bayer Healthcare LLC, the makers of Advantage® II] [OR]

[Advantage® II is a registered trademark of Bayer Healthcare LLC]}

[*[Brand Name] [This product] contains [imidacloprid and pyriproxyfen], the active ingredients used in

*[Advantage® II] [Advantage® II Kitten] [Advantage® II Small Cat] [Advantage® II Large Cat]**

{Note to reviewer: Text for footnote statement one}

[*[Brand Name] [This product] is not manufactured or distributed by Bayer Healthcare LLC, the makers of

[Advantage® II] [Advantage® II Kitten] [Advantage® II Small Cat] [Advantage® II Large Cat]

{Note to reviewer: Text for footnote statement two}

[Advantage® II] [Advantage® II Kitten] [Advantage® II Small Cat] [Advantage® II Large Cat]

is a registered trademark of Bayer Healthcare LLC.]

[End Optional Active Ingredient Reference Statements]

[Flea Marketing Claims]

[Prevents further flea infestation for up to [[four][4] weeks][1 month] with [just] one treatment]

[Prevents further flea infestation for up to [[four][4] weeks][1 month] with [just] one application]

[One treatment prevents further flea infestation for a month]

[Prevents flea re-infestations for 30 days [1 month]]

[For the prevention and treatment of Flea Infestations]

[[Brand Name] Prevents further flea infestation for [[four][4] weeks][1 month]]

[Kills fleas within 12 hours on cats [and prevents further infestations for up to [[4][four] weeks][[1][one][a] month]]

[Kills fleas within 12 hours [of application][on cats]]

[Kills reinfesting fleas within 2 hours]

[Kills [adult] fleas before they lay eggs]

[[Brand Name][This product] kills fleas and may reduce the incidence of a hypersensitivity skin disorder called flea allergy dermatitis (FAD), which may be caused by the feeding activity of fleas on cats]

[Contact with treated cat kills flea larvae]
 [Apply monthly [for effective flea control]]
 [Apply monthly [to control and prevent fleas]]
 [Apply monthly treatments for optimal control and prevention of fleas]
 [Kills fleas]
 [Kill fleas within 12 hours, continues to kill for up to 4 weeks]
 [Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]
 [Kills fleas, which may be a source of flea allergy dermatitis, within 12 hours]]
 [Controls existing flea infestation by killing adult fleas]
 [Active against fleas]
 [Kills fleas on cats and kittens over 8 weeks [old][of age] and 2-5 or 5-9 or over 9 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}
 [Kills fleas on cats] {weight range depends upon appropriate ml/fl oz package size}
 [(Begins/Starts) working through contact]
 [[Brand Name] Offers protection against fleas]
 [Flea control for cats]
 [Flea control for cats and kittens over 8 weeks [old][of age] and 2-5 or 5-9 or over 9 lbs[pounds]]
 {weight range depends upon appropriate ml/fl oz package size}
 [Once per month topical flea treatment for cats]
 [Monthly topical flea treatment for cats]
 [Once-a-month topical treatment for cats]
 [Flea control for cats and kittens over 8 weeks [old][of age] and 2-5 or 5-9 or over 9 lbs[pounds]]
 {weight range depends upon appropriate ml/fl oz package size}
 [Flea control for cats and kittens 8 weeks [of age] or older and 2-5 or 5-9 or over 9 lbs[pounds]]
 {weight range depends upon appropriate ml/fl oz package size}
 [[Once per month][Monthly] topical flea treatment for cats over 8 weeks [old][of age] and 2-5 or 5-9 or over 9 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}
 [[Once per month][Monthly] topical flea treatment for cats 8 weeks [of age] or older and 2-5 or 5-9 or over 9 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}
 [Once-a-month topical [treatment] [for] flea prevention and treatment for cats 8 weeks [of age] or older and 2-5 or 5-9 or over 9 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}
 [[Brand Name][This product] is for the treatment and prevention of fleas on cats over 8 weeks [old][of age] and 2-5 or 5-9 or over 9 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}
 [[Brand Name][This product] is for the treatment and prevention of fleas on cats 8 weeks [of age] or older and 2-5 or 5-9 or over 9 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}
 [Prevents and treats flea[s] [infestations]]
 [Kills reinfesting fleas on cats within 2 hours]
 [For the prevention and treatment of Flea Infestations]
 [[Brand Name] Prevents further flea infestation for up to [[four][4] weeks]] [[1][one][a] month]]
 [Controls existing infestations by killing adult fleas for 30 days]
 [Controls existing flea infestations on cats and protects against further infestations]
 [Use [of Brand Name][of this product]] kills fleas and may reduce the incidence of flea bite hypersensitivity [and][or] [flea allergy dermatitis] [FAD]]
 [Use [of Brand Name][of this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]
 [Monthly treatment [with Brand Name][with this product] kills fleas and may reduce the incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]
 [May be used year-round for control of fleas]
 [Kills fleas before they lay eggs]

[IGR Marketing Claims]

[Prevents flea eggs from hatching]
[Prevents flea eggs from developing into [biting] adult fleas]
[Prevents the development of flea eggs into [biting] adult fleas]
[Prevents the development of flea larvae into [biting] adult fleas]
[Controls existing flea eggs]
[Kills flea eggs]
[Prevents the development of new fleas in the cat's environment]
[[Brand Name][This product] contains Pyriproxyfen [PPF] [an insect growth regulator (IGR)] to kill flea eggs [and protect against reinfestation]]
[Targets multi-stages of the flea lifecycle]
[Controls multi-stages of flea lifecycle]
[[Brand Name][This product] is a flea ovicide, larvicide, and adulticide]
[Provides multi-stage flea control]
[Kills [flea eggs and] flea larvae]
[Breaks the flea life cycle] [icon]
[Prevents multi-stages of the flea life cycle from developing]
[Provides comprehensive flea prevention]
[Provides comprehensive flea control]
[[Brand Name][This product] inhibits the immature flea life stages (except pupae) from developing, preventing them from becoming [biting] adult[s] [fleas]]
[Controls existing flea eggs and fleas and prevents future infestations for 4 weeks [1 month] [30 days]]
[Monthly treatment controls existing flea eggs and fleas and prevents future infestations for 4 weeks [1 month] [30 days]]

[COMBO Marketing Claims]

[2-way protection kills adult fleas and flea eggs]
[[2 –Way] [Vet Quality] Protection for up to 1 Month]

[3-way flea protection kills adults, larvae and eggs]
[Kills flea eggs, larvae, and [adult] fleas]
[Kills [adult] fleas, [and] flea eggs, [and flea larvae]]
[Kills [adult] fleas, flea eggs and flea larvae for up to four [4] weeks][1 month]]
[Kills [adult] fleas, larvae, and eggs [, providing three-way protection]]

All Other Marketing Claims]

[Apply to [cats and] kittens over 8 weeks old and 2-5 or 5-9 or over 9 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}
[Apply to [cats and] kittens 8 weeks or older and 2-5 or 5-9 or over 9 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}
[[Formulated for] Cats and Kittens Over 8 Weeks [Old][of Age] and 2-5 or 5-9 or over 9 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}
[[Formulated for] Cats and Kittens 8 Weeks [of Age] or Older and 2-5 or 5-9 or over 9 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}
[Can be used on kittens over 8 weeks [old][of age] [or] 8 weeks [of age] or older and 2-5 or 5-9 or over 9 lbs[pounds] {weight range depends upon appropriate ml/fl oz package size}
[The Only Flea Protection You Need For Your Cat[s] When Applied Monthly!]
[Convenient] [Convenient, easy to apply topical solution]
[Easy application] [Easy to apply product]
[Easy to Use [Application]]
[One Step Hassle Free Protection!]
[Waterproof]

[Kills fleas even if your cat gets wet]
 [Remains effective, even after [bathing,][shampooing,] water immersion, or exposure to [sunlight]
 [and][or] rain]
 [Fragrance[-]free]
 [Once a month treatment]
 [Apply once every [4 weeks] [month] [30 days]!]
 [4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
 [For year-round protection, apply [Brand Name][this product] monthly]
 [One tube [vial][pipette]] [1 Month Supply]
 [Two tube [vials][pipettes]] [2 Month Supply]
 [Three tube [vials][pipettes]] [3 Month Supply]
 [Four tube [vials][pipettes]] [4 Month Supply]
 [Five tube [vials][pipettes]] [5 Month Supply]
 [Six tube [vials][pipettes]] [6 Month Supply]
 [9 tube [vials][pipettes]] [9 Month Supply]
 [12 tube [vials][pipettes]] [12 Month Supply]
 [24 tube [vials][pipettes]] [24 Month Supply]
 [Direct to skin [tube][vial][applicator][pipette]]
 [Easy to Use] [tube][vial][applicator][pipette]
 [No-mess [open] [tube][vial][applicator][pipette]]
 [Clip-tip design [tube][vial][applicator][pipette][!]]

[Consumer Value Marketing Claims]

[Coupon Inside]
 [Save Now!]
 [Value Size]
 [Club Size]
 [Bonus Size]
 [Club Pack]
 [Great Value]
 [Better Value]
 [Bonus Pack]
 [Bonus Buy]
 [[1][2][4][6][7][8][9][X] pack]
 [Twin Pack]
 [Try Now, Save Later!]
 [(x) + (x) bonus pack!]
 [Buy more and save!]
 [Buy X Get Y Free]
 [Buy 3 get 1 free]
 [(x)% (More) (Free)!]
 [33% more free]
 [(x) Dose(s) Free!]
 [(x) Day(s) (Free)!]
 [(x) Month(s) Free!]
 [(x) Day(s) of treatment- Free!]
 [(x) Tube(s) Free!]
 [(x) Applicator(s) Free!]
 [(x) Application(s) Free!]
 [[New!] {only for use for 6 months from date of registration}]

{END – FRONT PANEL}

BACK PANEL/SIDE PANEL

Cats Spot On Imidacloprid + Pyriproxyfen

[The active ingredients in [Brand Name][this product] are imidacloprid and pyriproxyfen. This product is formulated to control fleas [adult fleas, flea eggs, and flea larvae] on cats. [[Brand Name][This product] kills fleas within 12 hours and prevents further flea infestations for [up to] [[4][four]weeks][1][one] month][30 days].]

READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON CATS AND KITTENS 8 WEEKS OF AGE OR OLDER.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on cats only. Individual sensitivities, while rare, may occur after using ANY pesticide product for cats. Do not treat your cat with more than one pesticide product at a time. Over dosing your cat can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing cats.

FIRST AID

If Swallowed

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

If In Eyes

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

If on Skin or Clothing

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-775-9416 for emergency medical treatment information.

NOTE TO PHYSICIAN

Treat the patient symptomatically.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

Restrictions:

- **DO NOT ALLOW CHILDREN TO APPLY PRODUCT.**
- Do not use on animals other than cats.
- Do not allow your cat to ingest this product.

- Do not reapply for [[four] [4] weeks][30days].
- Do not use on kittens under 8 weeks of age. Do not apply to cats weighing less than 2 [5][9] lbs.
- Use entire contents of tube [vial][applicator][pipette] on each cat. Do not split one tube [vial][applicator][pipette] between two cats. Do not use multiple tube [vial][applicator][pipette]s on one cat.
- Weigh your cat to be sure you are applying the right dose formulated for the weight of your cat.
- Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.
- Do not have contact or allow children to have contact with the treated area until completely dry.

Side Effects: Monitor your cat after application. [Some cats may experience temporary startle effects when any product is applied.] Cats may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your cat with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-775-9416. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your cat and continue to monitor your cat for the next 24 hours.

{OUTER PACKAGING}

How to Open:

1. Remove product tube[s] [vial[s]][applicator[s]][pipette[s]] from the package.
2. Separate one tube [vial][applicator][pipette] from the others. Hold the tube [vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Hold cat with one hand and use the other hand to apply the solution.
2. Invert the tube [vial][applicator][pipette] and use the narrow end to par the cat's hair.
3. Squeeze tube [vial][applicator][pipette] firmly to apply all of the solution [on] [to] the cat's skin as a spot between the shoulder blades.

{For cartons containing 0.23 mL (0.0078 fl oz) applicator tubes}

Only For Cats Weighing 2 [-][to] 5 lbs. Do not apply to Cats weighing less than 2 lbs.

[including small cats or kittens, only 8 weeks or older] Apply one tube [vial][applicator] [pipette] 0.23 mL (0.0078 fl oz) directly to skin as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

{For cartons containing 0.4 mL (0.014 fl oz) applicator tube}

Only For Cats Weighing 5 [-][to] 9 lbs. Do not apply to Cats weighing less than 5 lbs.

[including small cats or kittens, only 8 weeks or older] Apply one tube [vial][applicator] [pipette] 0.4 mL (0.014 fl oz) directly to skin as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

{For cartons containing 0.8 mL (0.027 fl oz) applicator tube}

Only For Cats Weighing Over 9 lbs. Do not apply to cats weighing less than 9 lbs. Do not use more than one tube [vial][applicator][pipette] on cats greater than 9 lbs. Apply one tube

[vial][applicator][pipette] 0.8 mL (0.027 fl oz) directly to skin as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

FREQUENCY OF APPLICATION

[Use [Brand Name {or} this product] monthly for control of flea[s] [infestations].]
[[Studies show that] [Brand Name {or} This product] kills fleas within 12 hours of application and [lasts {or} protects] for [up to] [[four][4] weeks][30 days][one month].]
[[Brand Name {or} This product] kills reinfesting fleas within [2][two] hours and prevents further infestations of fleas [for [up to] [[four][4] weeks][30 days][one month]].]
[[Brand Name {or} This product] [targets multiple flea life stages] [and] [kills flea eggs and larvae before they develop into biting adults].]
[[Brand Name][This product] breaks the flea life cycle by killing flea eggs, flea larvae, and adult fleas.]
[If your cat is at high risk for flea reinfestation [, or in a highly infested environment], apply monthly.]
[Apply monthly for effective flea control.]
[[Brand Name {or} This product] is waterproof and remains effective, even after water immersion or exposure to sunlight [and][or] [rain].]
[Allow treated area to dry thoroughly.]

[How to Apply – May contain graphics illustrating product use, e.g., cat with a drop falling onto its neck from a tube/vial on front, side, or back carton label and/or applicator labeling.]

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove [tube][vial][applicator][pipette] from pack until ready to use. Store in a cool (below 77°F/[25°C]), dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: If empty: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Tevra is committed to providing high quality products. To the extent consistent with applicable law, Tevra makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Tevra, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: Tevra Brands Pet Owner Response, 401 N 1st St, LaSalle, Colorado, 80645 [Satisfaction Guaranteed.] [If you are not satisfied, we will make it right with a replacement or refund.]

In Case of Emergency, call: 1-800-775-9416

Coupon(s) inside or on outside of box]

Non-Emergency, call: 1-844-276-3290

[Made in USA With Global Materials]

[Distributed by:] [Manufactured by:]

Tevra Brands, LLC

LaSalle, Colorado, 80645

EPA Reg. No.

EPA Est. No. 92413 - xxx

[BAR CODE AREA]

{END - BACK/SIDE PANEL}

{START – ADDITIONAL OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE OR INSERT}

[Clip. Part. Squeeze.]

[Easier-than-ever applicator lets you **clip** the tip, **part** the fur and **apply** directly to the skin – putting proven flea protection where it needs to be.]

[Application Instructions]

How to Open:

1. Remove product tube[s] [vial[s]][applicator[s]][pipette[s]] from the package.
2. Separate one tube [vial][applicator][pipette] from the others. Hold the [tube][vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Hold cat with one hand and use the other hand to apply the solution.
2. Invert the tube [vial][applicator][pipette] and use the narrow end to part the cat's hair.
3. Squeeze tube [vial][applicator][pipette] firmly to apply all of the solution [on] [to] the cat's skin as a spot between the shoulder blades.

Look at the Label [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist

- [1] Read the label completely and follow directions
- [2] Weigh your cat
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment {or} application] to avoid chance of ingestion
- [6] Do NOT split [tube][vial][applicator][pipette] between cats][and use the ENTIRE [tube][vial][applicator][pipette] contents]

[Brand Name][This product]

[Monthly reminder card]

[1][2][3][4][5][6][12][24][Month [Treatment] [Application] Tracker][Carecard]

[For year round protection apply [Brand Name][this product] monthly.]

[Cat's Name (Empty blank for owner to fill in name)]

[Cat's Weight (Empty blank for owner to fill in name)]

[First][1st] [Second][2nd] [Third][3rd] [Fourth][4th] [Fifth][5th] [Sixth][6th] [Seventh][7th]

[Eighth][8th] [Ninth][9th] [Tenth][10th] [Eleventh][11th] [Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)

[Application Date] [Date of Application]

[Calendar stickers with Brand Name]

[Place stickers on your calendar as a reminder to reapply [Brand Name][this product] in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Place sticker on your calendar [or refrigerator] to remind yourself to apply [Brand Name][this product] to your cat]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days, the reminder light will blink, reminding you to reapply [Brand Name][this product]. Press the button once

and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

[optional graphic may or may not appear anywhere on the finished label of Adult Flea, Fleas, Flea eggs and/or Flea Larvae, Flea life cycle diagram, Flea Life Cycle, Refund or replacement of product {text footnote to satisfaction guaranteed graphic}]

{END – ADDITIONAL OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE OR INSERT}

TUBE/VIAL LABEL

**Cats Spot On
Imidacloprid + Pyriproxyfen**

{Front Label}

Brand Name {for Cats}

2-5 [5-9][>9] lbs. ≥ 8 wks

Imidacloprid 9.10%, Pyriproxyfen 0.46%

0.0078 fl oz {or} 0.014 fl oz {or} 0.027 fl oz

{label code}

{Back Label}

KEEP OUT OF REACH OF CHILDREN

CAUTION Read directions and precautions
on package. Use scissors to open.

EPA REG. No. 92413 - xxx {label code}

{EPA REG No may be on either the front or back label}

{label code refers to Tevra's product code number assigned to each product}

{END – TUBE/VIAL LABEL}



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

| | |
|---|--|
| Applicant's/Registrant's Name, Address, and Telephone Number Tevra Brands, LLC; 401 1st St. LaSalle CO USA, 80645 | EPA Registration Number/File Symbol 92413-x |
| Active Ingredient(s) and/or representative test compound(s) Imidacloprid and Pyriproxyfen | Date August 10, 2016 |
| General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Topical application to cats | Product Name TEVRA Imidacloprid + Pyriproxyfen Spot on for cats |

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

| | | |
|-----------|-------------------------|--|
| Signature | Date August 10, 2016 | Typed or Printed Name and Title Dr. Olaf Hansen, VP R&D Tevra Brands, LLC |
|-----------|-------------------------|--|



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the complete form to this address.

Certification with Respect to Citation of Data

| | |
|---|--|
| Applicant's/Registrant's Name, Address, and Telephone Number Tevra Brands, LLC c/o Pyxis Regulatory 4110 136th St. Ct. NW Gig Harbor, WA 253-8537369 | EPA Registration Number/File Symbol/ 92413-10 |
| Active Ingredient(s) and/or representative test compound(s) Imidacloprid, Pyriproxyfen | Date Dec. 26, 2017 |
| General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Residential indoor | Product Name TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats |

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statements (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have including with this form a list of companies send offer of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

| | |
|--|---|
| <input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose). | <input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used). |
|--|---|

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (II) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

| | | |
|---------------|-----------------------|---|
| Signature | Date Dec. 26, 2017 | Typed or Printed Name and Title Ann M. Tillman Agent |
|---------------|-----------------------|---|



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

| | | | | | |
|--|--|---|---|--------|--------------------|
| Date 8/10/2016 | EPA Reg No./File Symbol 92413-x | Page 1 of 2 | | | |
| Applicant's/Registrant's Name & Address Tevra Brands, LLC, 401 1st St. LaSalle CO USA 80645 | | Product TEVRA Imidacloprid + Pyriproxyfen Spon on for Cats | | | |
| Ingredient Imidacloprid (CAS# 138261-41-3) and Pyriproxyfen (CAS# 95737-68-1) | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| | Group A Chemistry | | | | |
| 830.1550, 830.1600 | Product Identity & Composition, Description of Materials | 49967601 | Tevra Brands, LLC | OWN | |
| 830.1650, 830.1670, 830.1750 | Formulation Process, Impurities, Certified Limits | 49967601 | Tevra Brands, LLC | OWN | |
| 830.1800 | Enforcement Analytical Method IMI and PPF | 49967602 | Tevra Brands, LLC | OWN | |
| | Group B Chemistry | | | | |
| 830.6302, 830.6303, 830.6304 | Color, Physical State, Odor | 49967603 | Tevra Brands, LLC | OWN | |
| 830.6314, 830.6315, 830.6316 | Oxidation/Reduction, Flammability, Explodability | 49967603 | Tevra Brands, LLC | OWN | |
| 830.6319, 830.6321, 830.7000 | Miscibility, Dielectric Breakdown Voltage, pH | 49967603 | Tevra Brands, LLC | OWN | |
| 830.7100, 830.7300 | Viscosity, Density | 49967603 | Tevra Brands, LLC | OWN | |
| 830.6317, 830.6320 | Storage Stability and Corrosion Characteristics | to be conducted | | | |
| 870.1100 | Acute Oral LD50 | cite | Pet Logic L.L.C. | PAY | |
| 870.1200 | Acute Dermal LD50 | cite | Pet Logic L.L.C. | PAY | |
| 870.1300 | Acute Inhalation LD50 | cite | Pet Logic L.L.C. | PAY | |
| 870.2400 | Acute Eye Irritation | cite | Pet Logic L.L.C. | PAY | |
| 870.2500 | Acute Skin Irritation | cite | Pet Logic L.L.C. | PAY | |
| Signature | | | Name and Title Dr. Olaf Hansen, VP R&D Tevra Brands, LLC | | Date 08/10/2016 |



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

| | | | | | |
|--|---|-------------|---|--------|--------------------|
| Date 8/10/2016 | | | EPA Reg No./File Symbol 92413-x | | Page 2 of 2 |
| Applicant's/Registrant's Name & Address Tevra Brands, LLC, 401 1st St. LaSalle CO USA 80645 | | | Product TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats | | |
| Ingredient Imidacloprid (CAS# 138261-41-3) and Pyriproxyfen (CAS# 95737-68-1) | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 870.2600 | Dermal Sensitization | cite | Pet Logic L.L.C. | PAY | |
| 810.3300 | Treatments to control pests of humans or pets | cite | Pet Logic L.L.C. | PAY | |
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| Signature | | | Name and Title Dr. Olaf Hansen, VP R&D Tevra Brands, LLC | | Date 08/10/2016 |

(A)

EPA
 United States Environmental Protection
 Agency
 Office of Pesticide Programs (H7505C)
 Washington, DC 20460

☐
☒
☐
Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide:**Section I**

| | | | |
|--|--|---|--|
| 1. Company/Product Number Tevra Brands, LLC / 92413-10 | | EPA Product Manager Venus Eagle | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Tevra Brands, LLC / TEVRA Imidacloprid + Pyriproxyfen Spot on for Cats | | PM# 1 | |
| 5. Name and Address of Applicant (Include ZIP Code) Central Garden & Pet 1501 East Woodfield Road, Suite 200 West Schaumburg, Illinois 60173 | | 6. Expedited Review. In accordance with FIFRT Section 3©(3) (b)(1), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ | |
| <input type="checkbox"/> Check if this is a new address | | | |

Section II

| | |
|--|--|
| <input checked="" type="checkbox"/> Amendment - Explain below | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application. |
| <input type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - explain below. |

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Central Garden & Pet hereby submits two studies on Child Resistant Packaging to support amendment of the Tevra product to be manufactured at our facility (EPA Est. No. 2724-TX-01). These studies are submitted in support of the amendment of EPA Reg. No. 92413-10 to allow production in CRP at our Texas plant.

For questions, please contact James McFadden, Tel: (847) 330-5369 or E-Mail: jmcfadden@central.com

Section III

| | | | |
|--|--|--|---|
| 1. Material This Product Will Be Packaged In: | | 2. Type of Container | |
| Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No. | Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>cardboard</u> |
| *Certification must be submitted. | | If "Yes," Unit Package wgt. 0.0078, 0.014 or 0.027 fl. oz. | No. per container |
| 3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) of Retail Container 1,3,4, 6 or 8 of 0.0078 and 0.014 fl. oz.; 3,4,6 or 8 of 0.027 fl. oz. | 5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product |
| 6. Manner In Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled | | Other (printed on cardboard) | |

Section IV

| | | |
|--|---|--|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | |
| Name James McFadden, Ph.D. | Title Director, Regulatory Affairs | Telephone No. (Include Area Code) (847) 330-5369 |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | 6. Date Application Received (Stamped) |
| 2. Signature  | 3. Title Director, Regulatory Affairs | |
| 4. Typed Name James McFadden, Ph.D. | 5. Date December 8, 2017 | |

| | | | |
|--|---|---|-----------------------|
|  | United States Environmental Protection Agency Washington, DC 20460 | <input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other | OPP Identifier Number |
|--|---|---|-----------------------|

Application for Pesticide – Section I

| | | |
|--|---|--|
| 1. Company/Product Number 92413-10 | 2. EPA Product Manager V. Eagle | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats | PM# PM 1 | |
| 5. Name and Address of Applicant (include ZIP Code) Tevra Brands, LLC c/o Pyxis Regulatory Consulting Inc. 4110 136 th St. Ct. NW Gig Harbor, WA 98332 | | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ |

Section - II

| | |
|---|---|
| <input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification – Explain below. | <input type="checkbox"/> Final printed labels in response to _____ Agency letter dated _____ <input type="checkbox"/> “Me Too” Application. <input type="checkbox"/> Other – Explain below. |
|---|---|

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)


Notification of alternate brand name per PRN 98-10. The alternate brand names are “Vetality Advotect II [Topicals] for Cats”, “Vetality ADVOTECT II [Topicals] for Cats”, “Tevrapet ActiSpot II [Topicals] for Cats”, and “Tevrapet ACTISPOT II [Topicals] for Cats”. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

| | | | | | |
|---|---|--|---|---|----------------------------|
| 1. Material This Product Will Be Packaged In: | | | | | |
| Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | 2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____ | | |
| * Certification must be submitted | | If “Yes” Unit Packaging wgt. 0.0078, 0.014, 0.027 fl oz | No. per container 1,3,4,6,8 | If “Yes” Package wgt. _____ | No. per container _____ |
| 3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container | | 4. Size(s) Retail Container Multiple sizes | | 5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled | | | | | |

Section - IV

| | | |
|--|---------------------------------|---|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | |
| Name Ann M. Tillman | Title Agent | Telephone No. (Include Area Code) |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | 6. Date Application Received <div style="text-align: center; border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;"> (Stamped) </div> |
| 2. Signature  | 3. Title Agent | |
| 4. Typed Name Ann M. Tillman | 5. Date Dec. 14, 2017 | |

| | | | |
|--|---|---|-----------------------------|
|  | United States Environmental Protection Agency Washington, DC 20460 | <input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other | OPP Identifier Number _____ |
|--|---|---|-----------------------------|

Application for Pesticide – Section I

| | | |
|--|---|--|
| 1. Company/Product Number 92413-10 | 2. EPA Product Manager V. Eagle | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Tevra Imidacloprid + Pyriproxyfen Spot On for Cats | PM# 1 | |
| 5. Name and Address of Applicant (include ZIP Code) Tevra Brands, LLC c/o Pyxis Regulatory Consulting Inc. 4110 136 th St. Ct. NW Gig Harbor, WA 98332 | | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ |

Section - II

| | |
|---|--|
| <input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification – Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> “Me Too” Application. <input type="checkbox"/> Other – Explain below. |
|---|--|


Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Notification of alternate brand name per PRN 98-10. The alternate brand names are “Vetality Advotect II for Cats”, “Tevrapet ActiSpot II for Cats”, “Vetality Advotect II Topicals for Cats”, and “Tevrapet ActiSpot II Topicals for Cats”. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

| | | | | | |
|---|---|--|---|---|----------------------------|
| 1. Material This Product Will Be Packaged In: | | | | | |
| Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | 2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____ | | |
| * Certification must be submitted | | If “Yes” Unit Packaging wgt. 0.0078, 0.014, 0.027 fl oz | No. per container 1,3,4,6,8 | If “Yes” Package wgt. _____ | No. per container _____ |
| 3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container | | 4. Size(s) Retail Container Multiple sizes | | 5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled | | | | | |

Section - IV

| | | | | | |
|--|-----------------------|---|--|--|---|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | | | | |
| Name Ann M. Tillman | Title Agent | Telephone No. (Include Area Code) _____ | | | |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | | | | 6. Date Application Received (Stamped) |
| 2. Signature  | | 3. Title Agent | | | |
| 4. Typed Name Ann M. Tillman | | 5. Date Dec. 22, 2017 | | | |



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

| | |
|--|--|
| Applicant's Name and Address Tevra Brands, LLC 9100 F Street, Suite 200 Omaha, NE 68127 | EPA File Symbol/Registration Number 92413-10 |
| | Product Name TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats |
| | Date of Confidential Statement of Formula (EPA Form 8570-4) Dec. 20, 2017 |

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Imidacloprid
Pyriproxyfen

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) of (3).

(3) Indicated by checking (A) or (B) below which paragraph applies:


☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

| Active Ingredient | Product Name | Registration Number |
|---|--|-----------------------|
| Imidacloprid | [REDACTED] | [REDACTED] |
| Pyriproxyfen | [REDACTED] | [REDACTED] |
| Signature  | Name and Title Ann M. Tillman Agent | Date Dec. 26, 2017 |